

APPENDIX K
COMPREHENSIVE OUTPATIENT REHABILITATION FACILITIES
INTEPRETIVE GUIDELINES

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INTERPRETIVE GUIDELINES
Comprehensive Outpatient Rehabilitation Facilities
Conditions of Participation

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Explanation of Conditions of Participation for
Comprehensive Outpatient Rehabilitation Facilities

I. COMPLIANCE WITH STATE AND LOCAL LAWS (42 CFR 488.54)

A. General.--In order to assure that the Comprehensive Outpatient Rehabilitation Facilities (CORF) and staff furnishing services are in possession of current licenses as required by State and local laws, licenses should be available for review. Compliance with this condition may have a bearing on other conditions; e.g., comprehensive rehabilitation program (42 CFR 488.58) and physical environment (42 CFR 488.62).

B. Major Sources of Information

1. State and local laws governing health care; building, fire and safety codes;
2. Applicable State and local licenses and organization personnel records containing up-to-date information; and
3. Written policies pertaining to communicable and reportable diseases, conforming to applicable State and local laws.

C. Standards

Standard (a): Licensure of Facility.--Ascertain that all State and local licenses, permits and approvals which govern the facility's operation are current and valid. The facility must meet all building, fire and safety codes where these are required for licensure before a facility would be eligible for certification. If the proper authorization(s) has not been granted, or has been temporarily revoked or suspended, the facility should be found in noncompliance with this standard, Condition I, Compliance with State and local laws (§488.54) should be marked not met and the facility should be refused admission into the program or termination proceedings should be initiated, whichever is appropriate.

If a facility has been issued a provisional license, permit or approval, document the reason for this issuance including the limitation(s) imposed on the facility's operation. Determine whether the limitation(s) prevents the facility from complying with the conditions of participation. If so, mark the applicable condition(s) and/or standard(s) in accordance with the instructions found in §2300ff.

Facilities exempt from State licensure, must be approved by the State as meeting the standards established for licensure. Examples of exempted facilities may include facilities that operate on a Federal reservation under agreement with the Department of Health and Human Services and facilities operated by a State, city or county health department.

Standard (b): Licensure of Personnel.--Personnel providing services at the CORF must be licensed or registered where applicable. This includes employees, independent contractors and individuals from organizations with which the CORF has an arrangement to provide services. Review a central State listing or other evidence such as wallet size identification cards to verify licensure or registration of personnel.

II. GOVERNING BODY AND ADMINISTRATION (42 CFR 488.56)

A. General.--The CORF must have a governing body which is responsible for its policies and operation, and which appoints an individual to act as the facility administrator. A group of professional personnel must develop and review policies that govern the CORF services.

The governing body is the Board of Directors or Trustees of a corporation or the owner(s), in the case of a proprietary agency or others who assume legal responsibility for the facility. Assess the effectiveness and adequacy of the governing body's management and operation of the facility by reviewing documentation of the governing body's activities. This documentation should include minutes of the governing body, policy statements, bylaws and delegations of authority. While there are no requirements that the governing body follow a prescribed meeting schedule, there should be evidence that the governing body takes an active role in the overall operation of the CORF. This includes the development and review of the institutional budget plan, and knowledge of and concurrence with all patient care and major operational policies. Place the names of governing body members in the space provided.

B. Major Sources of Information

1. Articles of incorporation, bylaws, policy statements, etc.
2. Minutes of governing body, staff and patient care policy meetings

3. Organization chart showing administrative framework
4. Personnel records -- job descriptions and personnel qualifications
5. Institutional budget plan
6. Management contracts
7. Patient care policies
8. Clinical records

C. Standards

Standards (a): Disclosure of Ownership.--The facility must disclose certain information about its ownership and control in complying with 42 CFR Part 420, Subpart C. Review the Ownership and Control Interest Statement, HCFA-1513 (Exhibit 6A) carefully for completeness prior to the survey. Instructions for completion are contained on the form. Follow the procedures in Sections 2130 and 2140 for obtaining, collecting and reviewing the HCFA-1513. Failure on the part of the CORF to fully disclose ownership may result in the withdrawal of eligibility status for program participation or termination of an existing CORF provider agreement.

Standard (b): Administrator.--The governing body must appoint an administrator who has responsibility for the overall management of the facility and retains professional and administrative responsibility for all personnel providing facility services. The qualifications of an administrator may vary among facilities, i.e., some administrators may be health professionals while others may be business managers. The administrator's basic responsibility regardless of the field of expertise, is to assure that services are rendered in accordance with CORF policies and that there is efficient utilization of resources and coordination of services. The administrator should have a thorough working knowledge of the overall operation of the facility, including the scope of services provided, policies governing these services, budgetary and fiscal matters and the utilization and qualification of personnel. Discussion with the administrator will assist in determining depth of facility knowledge.

An administrator, especially of a large facility, generally functions on a full-time basis. However, a small facility may have a part-time administrator, e.g., one who also provides services as one of the professional personnel. Where this is the case, determine if the amount of time the administrator spends performing administrative functions is commensurate with the facility's scope of operations. If it is determined that

administrative functions are suffering, inform the facility that an adjustment of its present system is in order. This adjustment may require that the facility, for example, expand the administrator's hours, or alter its operation so that the administrator is able to more appropriately implement and enforce its policies and procedures. Facility policies must designate in writing an individual who acts on behalf of the administrator during a period of absence. If in a small facility, as noted above, the administrator also provides professional services, an individual to serve during periods when the administrator is not on the CORF's premises should be designated.

Standard (c): Group of Professional Personnel.--The group of professional personnel serves a very specific facility function, that is, to make certain that policies relating to patient care are realistic and best meet the needs of the facility and patients alike. Effective facility operation is dependent, in part, on workable policies especially those relating to: limitation of service capability, criteria for patient admission, etc. These policies must be developed and periodically reviewed by the group of professional personnel. The facility should be able to show that the group of professional personnel is carrying out its policy formulation and review function. The group must consist of at least one physician and one professional representing each of the services provided by the facility. The names of all group members must be available and evidence must confirm their participation in policy development and review. This evidence can be minutes of meetings or other documentation which reflects that this function is being carried out.

All or part of the group of professional personnel, or a group of similar composition, can serve as the facility's utilization review committee (see Condition VII, Standard (a)). Although a similarly comprised group not associated with the facility can perform the utilization review function, it cannot develop and periodically review the facility's policies.

Standard (d): Institutional Budget Plan.--In reviewing the facility's institutional budget plan (i.e., budget and/or a capital expenditure plan), consideration is to be given solely to its presence, and its annual review by the governing body. It is not important how this material is identified, just that it exists. Do not determine specific item appropriateness and do not review for substance.

The budget and/or plan must be prepared under the direction of the governing body by a committee composed of at least one member of the governing body and at least one member of the administrative staff.

The administrative representative is not required to have accounting, planning, or any other specific professional background, but should be in a management position. Documentation should verify that a governing body representative has been designated to work with a representative of the administrative staff.

For purposes of this section, a capital expenditure plan is for at least a three-year period, including the current and the two succeeding fiscal years. The period shown should correspond to the facility's budget fiscal year. A capital expenditure plan is required when an expenditure in excess of \$100,000 for this three-year period is expected. The administrator may state that there is no capital expenditure plan because no capital expenditure in excess of \$100,000 is anticipated. In this case, the appropriate part of the survey report form should be noted "Not Applicable" and the administrator's reason shown in the Explanatory Statements column.

Included as part of capital expenditures are the costs related to studies, surveys, designs, plans, working drawings, specifications and other activities essential to the acquisition, improvement, modernization, expansion or replacement of land, plan, building and equipment. Expenditures directly or indirectly related to capital expenditures, such as grading, paving, taxes assessed during the construction period and costs involved in demolishing or razing structures are also included. Transactions which are separated in time but are components of one overall plan or patient care objective are viewed in their entirety without regard to their timing. Other costs related to a capital expenditure include title, permit and license fees, broker commissions, architect, legal, accounting, and appraisal fees, interest, finance or carrying charges on bonds, notes and other costs incurred for borrowing funds. Where the costs of the above total \$100,000 or more, a capital expenditure plan must be developed.

Standard (e): Patient Care Policies.--These policies comprise the basic operating framework of the CORF and are critical to its effective operation. All policies must be in writing and documentation must verify the input of the group of professional personnel in policy development and review. Interview members of the professional staff to determine if they have a working knowledge of the policies. The policies should be current, compatible with the CORF's provision of services and be responsive to the needs of the patients. Copies of all patient care policies should be reviewed.

In brief, patient care policies must reflect the following:

- . all services rendered by the CORF including those which are rendered by employees or by others furnished under an arrangement;

- . a description of personnel tasks during medical emergencies and specific responsibilities, where assigned;
- . the types of drugs and biologicals usually kept on the premises, their use, their manner of storage, who has access to these materials and a procedure for periodic review to determine the date of limited substances;
- . all criteria governing patient admission, continuing care and discharge. These criteria should coincide with professional staffing and must be as specific as possible. Factors governing admission may include geographic areas, ambulatory status of patients, specific diagnoses, patient ability to carry through on a home program, etc. Criteria developed for discharge may follow along the lines of specific levels of progress (attainment of goals), need for higher level of care etc;
- . the manner in which clinical record documentation is to be prepared and maintained. At a minimum, policies should state that all personnel performing services (i.e., those defined in the conditions of participation) must sign any entry they place in the patient's clinical record regardless of whether such personnel are employees of the facility or others. Clinical records must be maintained so that easy access is afforded all CORF personnel;
- . a procedure for explaining a patient's treatment program to the patient and to the patient's family. In most cases this procedure would include a discussion of the diagnosis(es), the type and reasons for treatment, the treatment goal and the type of home program, where applicable, which will be developed. In general, unless the referring physician specifically notes that certain information is not to be revealed to the patient or family, the treatment program is to be discussed in detail and procedures are to be in effect for continuing discussions as they are warranted;
- . a policy that requires all patients to be under the care of a physician and that a plan of treatment for each patient must be in effect;
- . a procedure to assist the referring physician in locating another level of care for patients whose treatment has terminated and who are discharged; and
- . a procedure to ensure that the group of professional personnel reviews and takes appropriate action on recommendations from the utilization review committee regarding patient care policies.

Standard (f): Delegation of Authority.--The responsibility for overall administration, management and operation must be retained by the facility and not delegated to others. A CORF may delegate to others those

functions which do not, in any way, infringe upon its ability to direct and control all necessary administrative, management and operational activities. Those functions which may be delegated relate to financial management, specifically those areas noted in the regulation. A CORF may not, for example, appoint an individual to serve as an administrator who is an employee of another organization. This standard does not preclude the CORF from using personnel other than employees to furnish patient care. A contract between the CORF and another entity (e.g., a management company) for the delegation of financial management services must be in force. This contract must not be for a term that exceeds 5 years.

No provision of this contract should enable the entity to act on behalf of the CORF or give the entity any responsibilities that would enable it to alter in any way, normal operational activities.

III. COMPREHENSIVE REHABILITATION PROGRAM (42 CFR 488.58)

A. General--Ascertain that the CORF is providing a coordinated rehabilitation program. Assimilation of information from patient care policies, plans of treatment, clinical records and staff interviews will be necessary. Review a listing of CORF services to determine that the three required services (physicians' services, physical therapy and social or psychological services) are furnished and readily available.

B. Major Sources of Information

1. Patient care policies
2. Clinical records
3. Organization chart showing administrative facility framework.

C. Standards

Standard (a): Physician Services--Written documentation must indicate that a physician(s) who meets the qualifications in the conditions of participation performs the required physician services. Participation for at least one year in a residency program which provides training in the medical management of patients needing services such as orthopedics, neurology, neurosurgery, rheumatology, etc., meets the definition of facility physician. If physicians do not have this training, but wish to meet the definition by virtue of prior or concurrent experience in a rehabilitation setting, ascertain that this experience has been at least one year in length and consisted of activity such as developing plans of treatment, participation in patient case review conferences and establishing pertinent patient care policies. While it is preferable that this experience would have been full-time, part-time experience is acceptable. However, part-time experience should have been on a continuing weekly basis. The degree of time spent must confirm that required functions were accomplished.

Documentation must verify this training or experience. It might consist of a resume, certificates of training or letters acknowledging completion of training or experience. Review available material to verify compliance with physician qualification requirements.

The facility physician may be associated with the facility on either a part-time or full-time basis. If part-time, it is important to determine that the physician is effectively performing required responsibilities. Review the activities of the group of professional personnel, utilization review process, patient records and reports of case review conferences to ascertain the extent of physician participation in patient care activities. The extent of physician participation can be determined, in part, by the type and volume of patients, scope of services and need for consultation and medical care services. Normally, greater physician participation will be required in a facility where the patients have multiple chronic disabilities, require several services, and require frequent changes in the plan of care than in a facility where the patients have acute disabilities.

A facility physician may refer patients to the facility. CORFs may have a physician(s) providing physician services at the facility on a part-time basis and this physician(s) may have an office practice distinct from the CORF. In such cases this physician(s) may establish the CORF plan of treatment when referring patients to the CORF. If a plan of treatment has not been established by the referring physician, a facility physician is responsible for establishing a plan of treatment.

Diagnostic and therapeutic services furnished to an individual patient are not CORF physician's services and may be provided by physicians who do not meet the definition of facility physician.

Emergency physician services need not be performed by a facility physician. Rather, these services may be provided by another physician(s) or by paramedics with hospital emergency room back-up, or through other arrangements that ensures prompt delivery of emergency services. These mechanisms must be in writing, readily available and familiar to all staff. Emergency services must be available during the total operating hours of the CORF.

Standard (b) Plan of treatment--Every patient must have a plan of treatment established, either by the facility physician, the referring physician or both in collaboration. If a plan of treatment is not established for a patient referred to a CORF, the facility physician must establish one. Usually, a plan of treatment is written; however, it is acceptable in certain circumstances for a verbal order and plan to be telephoned to the CORF by the referring physician (if a facility physician is present when the patient arrives, this physician should develop the plan of treatment if one has not been developed). The time, date, referring physician's name and contents of

the verbal order must be documented and signed by the person receiving the order, and countersigned by the referring physician as soon as possible. It may not always be appropriate for facility professional staff to be involved in the development of the plan of treatment; however, in some facilities this is normal practice. It may also be normal practice for the physician to develop treatment procedures subsequent to professional personnel evaluation and recommendations. Therefore, it is acceptable for the initial plan of treatment to be written in a general nature, i.e., providing the goals and services to be performed. However, it must be rewritten later to include specific items such as precautions and the frequency, amount and duration of services. A plan of treatment in some form must be developed prior to the beginning of patient treatment. If specific information relative to frequency, goals, etc., is not routinely incorporated with the physician referral, inform the administrator and request that corrective action be taken to avoid a re-occurrence of this problem. The plan of treatment must include all of the services needed by the patient that meet the definition of CORF services. (CORF services are: physician; physical therapy; occupational therapy; speech-language pathology; respiratory; prosthetic; orthotic; social; psychological; nursing; drugs and biologicals; and supplies, appliances and equipment). For example, if a patient is in need of social services, physical therapy and speech-language pathology, all three services must be included in the CORF plan of treatment.

After treatment has begun, any change in the plan of treatment should be supported in the patient's clinical record by dated documentation signed by either the facility physician or by the referring physician. It should be noted in the patient's clinical record whether changes in the patient's condition, staff recommendations and/or results of a patient case review conference caused the change to be made. Any change in the patient's condition must be accompanied by an evaluation and, if necessary, a revision of the plan of treatment.

The 60-day review of the plan of treatment must be performed by a facility physician who certifies that the plan of treatment is being followed and that the patient is making progress in attaining the established goals. A facility physician, in most cases, will be more familiar with the CORF's services, and the patient's status, and will have easier access to the patient's record and professional staff opinions than the referring physician. However, the referring physician should always be given the opportunity to have continued input into the patient's treatment program. In this regard, CORF staff must communicate either verbally or in writing the results of the 60-day review to the referring physician. Verbal communication should be by either a facility physician or one of the professional personnel carrying out the plan of treatment. The referring physician's verbal concurrence, or revision of the plan of treatment should be documented in the patient's clinical record by the individual communicating with the referring physician. This documentation should include the date and the subject matter discussed. The referring physician's written response should be incorporated into the patient's clinical record. While it may be preferable to temporarily suspend services until receipt of the referring physician remarks, this may not always be

practical. Record reviews will be able to show whether the referring physician's remarks have been received timely. If there appears to be a trend developing which indicates these remarks are not timely, inform the administrator.

Standard (c): Coordination of Services.--Patients receive maximum benefit from a comprehensive outpatient rehabilitation program when services are provided in a coordinated manner. In most CORFs, a multi-disciplinary team of professional personnel provides several rehabilitation services to patients. The team may include full-time and part-time employees as well as non-employees functioning on either a full-time or part-time basis. It is, therefore, important that the facility take steps to assure that services are provided in an efficient, effective and coordinated manner. The facility must designate in writing one professional to oversee the coordination activities that the facility has developed. This responsibility can be performed concurrently with the assigned person's normal professional duties.

Frequency of clinical record entries may range from a brief entry in a patient's clinical record each day the patient receives treatment, to entries of longer intervals. The facility must establish some procedure detailing the frequency of clinical record documentation. Since this documentation may be used as one of the factors in determining the outcome of the 60-day plan of treatment review, entries should appear frequently enough during each 60-day period to provide an adequate picture of the care being given and the patient's status relative to established goals.

The frequency, format, and criteria for patient case review conferences may vary among facilities. These conferences generally will be convened to determine the appropriateness of continuing treatment, changing a plan of treatment, or to coordinate treatment activities. Conferences may routinely be scheduled for each patient after the patient has been undergoing treatment for a specified period of time or has had a specified number of treatments; or conferences may be scheduled only for patients who are not meeting anticipated goals, who need a different level of care, or who are receiving an intensive multi-service rehabilitation program. There must be a written policy regarding patient case review conferences, and it should be adhered to. Review past patient case review conference documentation and interview personnel regarding its utilization. There should be a formal procedure to familiarize all personnel treating the patient with the results of the CORF's coordination of service activity.

Standard (d): Provision of Services.--All patients must be referred to the CORF by a physician. The referral should contain the patient's medical history, current medical findings, diagnosis, contraindications to any treatment modality and rehabilitation goals, if determined. Current medical findings and a complete and appropriate medical history do not always accompany a physician's referral. In such cases, a qualified professional or a facility physician should obtain this information from the patient. Obtain additional necessary information through followup with the referring physician.

CORF services may be provided by employees or by others under arrangements, i.e., individuals from an organization that has a contract with the facility to provide services, and individuals that contract directly with the CORF. Professional personnel need not be expressly employed by a CORF or function under an arrangement exclusively for a CORF. Personnel may be associated with other organizations while they are associated with the CORF, but must be available during operating hours. For example, a principal(s) of a skilled nursing facility (SNF) may also own a CORF and share personnel between these two providers. This is permissible and satisfies compliance with regulations when these personnel are able to function exclusively for each provider in carrying out assigned responsibilities. This is especially important because each CORF is a separate identifiable provider and must independently meet the Conditions of Participation.

After determining the type of services the CORF provides, ascertain that it has the equipment and personnel necessary to adequately and effectively provide these services. Determine specific equipment requirements from the plans of treatment, and verify the presence of such equipment.

A facility need not own all of the equipment required for implementing the plan of treatment. It is permissible to rent or lease necessary equipment on an as needed basis, however, there must be evidence that this equipment was and is able to be readily obtained.

The number of qualified professionals and/or others needed to adequately and effectively provide services to patients accepted for is not to be determined by a simple proportion of staff to patients. It is to be based on knowledge of the types of patients treated, and the frequency, duration and complexity of treatment required.

When supportive personnel (i.e., aides) other than those that are noted in the personnel qualification section of the Conditions of Participation (see §485.70, formerly §488.70)) are used to assist qualified professionals, their duties, responsibilities and qualifications should appear in the facility's policies and be consistent with accepted standards and practices. All supportive personnel must be instructed in specific patient care techniques by appropriately qualified personnel.

This instruction depends on assigned responsibilities, education, experience and the types of patients treated. The appropriately qualified professional must be on the premises, and supervise the care given when supportive personnel are utilized. Verify this through a review of the treatment and staffing schedule. For example, when supportive personnel are used in conjunction with the furnishing of physical therapy services, a person meeting the qualification requirements of §485.70 (formerly §488.70) must be on the premises.

Changes which need to be made concerning the implementation of the plan of treatment may be initiated by qualified professional personnel. Assistant-level personnel (as defined in §485.70 (formerly §488.70)) must not initiate such changes without the approval of the appropriately qualified professional. Ideally, all professional personnel should be on the premises of the CORF when not providing offsite therapy services. When this is not the case, personnel must be available for duty on the CORF's premises as needed, and must be able to be contacted by telephone.

At least one qualified professional (or a combination of professionals) must be on the facility's premises during its hours of operation.

It may not be unusual to find that, in a CORF which furnishes a broad array of rehabilitation services, particular aspects of care are being furnished by several types of professionals. For example, registered nurses with special training in respiratory care or physical therapists may furnish respiratory therapy services. Occupational and/or physical therapists may engage in the design and development of orthotic and prosthetic devices.

The CORF is responsible for ensuring that a practitioner furnishing a particular service is qualified to do so under State law and does so within accepted professional standards and practices. Noncompliance with §485.58(d)(7) (formerly §488.58(e)(7)) raises serious questions concerning the CORF's ability to ensure patient safety and could lead to termination from Medicare. Carefully review the qualifications of a professional providing more than one CORF service. Determine the scope of the particular service and verify that the practitioner is qualified to provide the service, and that it is provided pursuant to State law and accepted professional standards and practices.

Standard (e): Scope and Site of Services.--In general, all services must be furnished on the premises of the CORF. The only exceptions are the home evaluation visit (see §2362) and, effective December 22, 1987, physical therapy, occupational therapy, and speech pathology services. The provision allowing offsite therapy services does not permit the CORF to establish extension locations and all records must be maintained on the premises of the CORF. The purpose of the home visit is to evaluate the home environment in relation to the patient's established treatment goals. The home visit

evaluation may include assessing the need for modifying the physical and/or social environment to maximize the patient's functional capability. The home, for purposes of this home evaluation visit, is the patient's legal residence. The visit may take place anytime between the implementation of the plan of treatment and the discharge of the patient. A patient who is periodically discharged and admitted for a chronic but stable problem would not normally receive more than one home evaluation visit, even though the patient may be receiving more than one service.

Notes in the patient's clinical record should indicate when the visit was made, by whom, its purpose and the results of the evaluation.

Also, the CORF must provide all the CORF services required in the plan of treatment. Since these services may be provided by personnel under arrangements, there should be minimal difficulty in obtaining personnel to provide services regardless of the infrequency of demand for the service. The unavailability of a service forces the patient to seek the service at another location. This is contrary to one of the purposes of the CORF legislation, i.e., to remedy the situation where beneficiaries needing several rehabilitation services are required to seek them at more than one location.

NOTE: When completing the CORF Survey Report Form (HCFA-360) do not mark standard 485.58(e) (tag number 1-555) "no" if the CORF provides physical therapy, occupational therapy or speech pathology services offsite. We will revise the HCFA-360 to include this offsite provision when it is reprinted.

Standard (f): Patient Assessment.--Verify that each patient is assessed by each qualified professional personnel involved in the patient's care prior to the implementation of the plan of treatment. Compare, on a sample basis, the date the plan of treatment was established to the date of the initial assessment by the appropriate professional defined in §485.70 (formerly §488.70). When the plan of treatment specifies several rehabilitation services, the professional personnel responsible for initiating the plan may be unable to complete their respective assessments on the same day. This may result in a lapse of several days between assessments. In these situations the plan of treatment may be initiated before all professionals have assessed the patient. For example, the physical therapist may complete an assessment of the patient and initiate the physical therapy service portion of the plan before the speech pathologist assesses the patient. Reasons for this time lapse may be due to scheduling conflicts, the patient's endurance, insufficient coordination or lack of communication among staff.

If an unreasonable time lapse occurs between assessments, determine the frequency, lengths, and reasons for the time lapse. Ascertain whether the time lapse is resulting in unnecessary patient visits, uncoordinated patient care or lengthy delays in implementing the complete plan of treatment.

A patient reassessment serves as a tool to present a comprehensive picture of the patient's status at a specific point in time. Because the reassessment usually consists of the same evaluative mechanisms (e.g., test procedures, measurements, professional observations and subjective information from patient) used in the initial assessment to obtain indicators of the patient's status, the patient's status at different points in time can be compared. Since a reassessment must be performed when significant changes in the patient's condition are noted, such a comparison is useful to determine whether the current plan of treatment is appropriate.

In contrast to the information obtained in a reassessment, periodic entries in the clinical record as required in §485.58(c)(3) (formerly §488.48(c)(3)) usually contain information such as a patient's reaction to treatment, general condition of patient, significant changes in patient's status and/or changes in the intensity of treatment. These entries provide in chronological order a picture of the patient's progress in relation to the care being given.

IV. CLINICAL RECORDS (42 CFR 485.60 (formerly 488.60))

A. General--The clinical record serves as a basis for documentation of care rendered to the patient and communication between all personnel furnishing services. Determine whether the content of the clinical record presents a total, or at a minimum, an adequate picture of the care being given.

B. Major Sources of Information

- o Active and closed clinical records
- o Policies regarding protection and retention of clinical records

C. Standards

Standard (a): Content--Examine a substantial number of both active and closed clinical records and ascertain that the required material is included. If any of the material required in this standard (§485.60(a) (formerly 488.60(a))) is absent from the clinical records, review additional records to determine the prevalence of such omissions. Record the number of records reviewed and

the number and types of deficiencies observed. In determining the number of records to be reviewed, be guided by the size of the CORF's patient caseload. The larger the caseload, the larger the review sample should be.

Each patient's record should contain a summary of each patient case review conference, where appropriate, and indicate the purpose and recommendation resulting from the conference. All reports generated as a result of any meetings concerning patient care issues should be dated, signed and made a part of the record.

Ascertain that periodic progress notes are entered in the clinical records at intervals commensurate with the type and frequency of treatment. These notes are to address the progress of the patient in attaining stated plan of treatment goals. Some facilities may require a brief entry in the clinical record each day the patient receives a treatment while other facilities may require routine progress reports at longer intervals. Ascertain the time interval between progress reports. Determine whether the time interval is impeding coordination and communication in patient care activities. Regardless of the frequency of progress notes, the notes should record the patient's status in relation to the stated treatment goals.

A discharge summary should include the date and reason for discharge, a brief summary of the patient's current status and, where applicable, details regarding referral of the patient to another level of care.

All information appearing in the clinical record must be dated, appropriately signed and promptly incorporated in the record.

Standard (b): Protection of Clinical Record Information.--Active and closed clinical records are to be stored where they are protected from fire and unauthorized use. Ascertain that there are written procedures governing the use of records which specify to whom the records or copies of records may be provided, the use to which the material may be put and the circumstances describing the return of such material. Determine that written patient consent is present to allow the release of all material not authorized by law.

Standard (c): Retention and Preservation.--Review the established policy for the preservation and retention of clinical records and verify that applicable State laws or regulations are met. The facility must provide for the maintenance of clinical records in cases where the CORF ceases to function.

V. PHYSICAL ENVIRONMENT (42 CFR 488.62)

A. General--Examine the structure housing the CORF to ascertain that it is maintained consistent with State and local building, fire and safety codes. Review the CORF policies and procedures regarding preventive maintenance and infection control to determine if they are compatible with the scope of services, the type of equipment used and type of patients accepted for treatment.

A CORF may be established on the premises of another health entity irrespective of whether this entity is already certified under Medicare as a provider or supplier of services. For example, a CORF may be established on the premises of a skilled nursing facility (SNF) and the SNF's owner(s) may either have legal responsibility for both the SNF and the CORF, or merely rent space within the SNF to the CORF's owner(s). In either situation, the CORF must be certified separately and be functionally and operationally independent. The regulatory definition of a CORF precludes the CORF, and another entity from mixing functions and operations in a common space during concurrent or overlapping hours of operation. Sharing of a common space is acceptable if the CORF is able to fully function without interruption during its scheduled hours of operation. Use of the CORF space by another entity, or host entity if the CORF is on the premises of another health facility, during CORF hours of operation is unacceptable. For example, space on the premises of a facility which is recognized as a provider of outpatient physical therapy/speech pathology (OPT/OSP) services may function as a CORF, if this space is not to be used for OPT/OSP purposes during the operating hours of the CORF.

In the same manner as space may be shared, equipment may also be shared. All common equipment must be available (on the premises of the CORF) during the CORF's hours of operation and not, at that time, be utilized by the other entity for any purpose. (Please refer to standard(d) page K-13 for an explanation of sharing of staff).

The CORFs must be surveyed pursuant to the CORF conditions of participation and all standards must be surveyed independent of any findings resulting from the completed survey of the other entity. That is, although there may have been no deficiencies noted during the survey of the other entity, this fact must not influence any determination with respect to the survey pursuant to the CORF conditions of participation.

B. Major Sources of Information

1. Applicable State and local laws
2. Inspection reports of State and local building and fire authorities
3. Organization policies and procedures regarding maintenance of equipment, buildings and grounds.

C. Standards

Standard (a): Safety and Comfort of Patients.--Review available reports of State and local personnel responsible for enforcement of building, fire and safety codes and verify that the CORF is in compliance with applicable codes. All areas occupied or accessible to the facility for use during emergency or non-emergency activity, including corridors and stairways, are to be protected by easily accessible fire extinguishers. Lights, supported by an emergency power source, must be placed at exits. Where there is a CORF established on the premises of another health entity, also survey those areas which are common to both, i.e., corridors, stairways, storage areas, etc.

The fire alarm system must be adequate to alert personnel in time for safe evacuation of the building. The system should consist of either a manual (pull type) fire alarm system with or without automatic fire department response, or an automatic detection system along with an audible manual alarm. Any system should have the capacity for manual activation that triggers an audible in-house alarm which alerts personnel, patients and the public to the present danger and need for action. Where the alarm system is activated by a disruption of the electrical system or in other ways dependent on it, an emergency power source with automatic triggering, e.g., battery or auxiliary generator, must be available to serve as a backup. In the absence of State or local requirements, the above systems are to be approved by the State Fire Marshall's Office.

The number of staff necessary to evacuate patients during an emergency depends largely on the number and types of patients scheduled to be on the premises at any one time. A patient population consisting largely of patients dependent

on assistive devices for ambulating (e.g., canes, crutches and walkers), wheelchair bound patients and other patients who would need assistance from CORF personnel for a quick, safe evacuation, would require the presence of more staff than a patient population which is dependent on ambulatory assistive devices.

An emergency power source must be supplied, e.g., by battery or auxiliary generator, to assure adequate lighting during emergency operation within the treatment areas or those passageways, stairwells and exits (as noted above) accessible to the CORF. In cases of power outage, the emergency power source should respond either automatically or require only minimal activation effort.

Verify that the temperature and ventilation is maintained at a comfortable level.

Standard (b): Sanitary Environment.--The facility must maintain a sanitary environment and establish a program to identify, investigate, prevent and control the cause of patient infections. Review the written policies and procedures regarding infection control and maintenance of a sanitary environment. Verify that they are sufficient in light of the volume and types of patients and services provided, and that there is consistency with current practices of infection control. Identify the individual or group responsible for establishing, implementing and monitoring the policies and procedures. The facility must monitor the infection control program to ensure that policies and procedures are being complied with and are consistent with currently accepted practices. Pay particular attention to the policies, procedures and reports concerning the care and debridement of wounds, and the cleaning and disinfection of equipment such as whirlpools and paraffin baths and respiratory therapy equipment.

Verify the general sanitation, cleanliness and orderliness of the premises and verify that clean and soiled linen is handled in an orderly and sanitary manner that will prevent the spread of infection. There must be an adequate supply of fresh linen (sheets, towels, pillow cases) which must be stored and processed separate from soiled linen. Soiled linen must be processed and stored in an area away from patients, personnel and the public.

Standard (c): Maintenance of Equipment, Physical Location and Grounds.--All equipment should be inspected by CORF personnel at least yearly or more frequently depending on equipment condition and its frequency of use. Written procedures regarding the preventive maintenance program must include the following: equipment to be inspected, a brief statement concerning the general inspection process and frequency of inspection for each piece of equipment. For all electrically powered patient care equipment, appropriate manufacturer's operating and maintenance information must be on file. Review this information and ascertain what specific manufacturer's recommendations, if any, are made for equipment calibration checks, periodic maintenance procedures, etc. Then, through copies of service repair statements or other documentation, determine whether such recommendations were followed.

The facility must be free of hazards to the health and safety of patients, personnel and the public, e.g., broken window and door panes, obstruction of passageways and dangerous floor surfaces, and any hazardous exterior walkways or parking areas. Hazards are to be brought to the attention of CORF personnel.

Standard (d): Access for the Physically Impaired.--Inspect the premises to verify whether the facility ensures safe access and adequate space to maneuver in waiting areas, treatment areas and toilet facilities for all physically impaired patients including those on stretchers or in wheelchairs. Make sure that at least one toilet facility is able to be used by ambulatory and nonambulatory patients, that is, grab bars are provided, elevated toilets seats are available, etc. Verify that doorways, stairwells, corridors are of adequate width to allow for safe movement of all patients, that stairwells are equipped with a handrail on at least one side and that at least one entrance is usable by individuals in wheelchairs. A wheelchair entrance must be equipped with a suitable ramp if needed.

VI. DISASTER PROCEDURES (42 CFR 488.64)

A. General.--A well developed disaster plan is to be documented and posted in areas accessible for continuing personnel review.

B. Major Sources of Information

1. Disaster plan
2. Documentation as to ongoing training sessions and dates of disaster drills

C. Standards

Standard (a): Disaster Plan.--Ascertain that the disaster plan is documented and includes the assignment of responsibilities to CORF personnel, evacuation routes, and procedures for the transfer of records and casualties. In addition, verify that the plan includes procedures for notifying community emergency personnel, procedures for leaving the facility and instructions regarding the location and use of alarms and fire fighting equipment. Interview staff to ascertain their familiarity with the plan. The plan should be posted where it can be easily seen by patients and the public.

The CORF is responsible for ensuring that all personnel (employees and others) are knowledgeable of their responsibilities and have been trained in carrying them out. The CORF must train and instruct all personnel in disaster preparedness responsibilities. Larger, more complex CORFs would most likely provide ongoing training more frequently than smaller CORFs. The date of training and names of those persons taking part are to be documented. Verify from this documentation that all personnel have been instructed and

trained in their responsibilities and that all new personnel are properly trained within 2 weeks of their first workday.

VII. UTILIZATION REVIEW PLAN (42 CFR 488.66)

A. General--Each facility must have in effect, a written utilization review plan. An established utilization review plan serves to indicate how well policies are functioning, how effective treatment regimens have been, and how well the CORF has adopted its particular program to selected patients.

B. Major Sources of Information

1. Clinical records
2. Written utilization plan

C. Standards

Standard (a): Utilization Review Committee--The committee must meet at least quarterly. It is the responsibility of the CORF to make sure that a facility physician participates in the review process, either as a primary review member or as a post review participant. Verify that a facility physician has been involved.

Standard (b): Utilization Review Plan--Ascertain that the plan contains specific procedures and standards necessary to perform the required evaluations. The number of cases selected for review and the frequency of reviews should be outlined in the plan. Cases reviewed should be representative of the types of patients treated at the CORF and the types of services provided.

Ascertain whether the utilization review plan is being followed. Reports and outcomes of evaluations should be reflected in the minutes of the utilization review committee. Those minutes should also indicate the extent to which the CORF program, policies and practices are being followed.

Results of utilization review activities should be made available to all professional personnel. Identify whether the results of the review prompted recommendations concerning CORF policies and practices and whether the recommendations were communicated to the administrator and governing body and the group of professional personnel (if different from utilization review committee).